

AMENDMENTS TO THE CLAIMS

Claim Listing:

1-8. (canceled)

9. (previously presented) A method for reducing undesirable hepatotoxic side effects inherent in anti-tumor therapy with Ecteinascidin 743 (ET-743) which comprises administering indole-3-carbinol or one or more derivatives or pharmaceutically acceptable salts thereof to a patient, wherein the indole-3-carbinol derivatives are selected from:

5-methyl-indole-3-carbinol, 5-ethyl-indole-3-carbinol, 5-propyl-indole-3-carbinol, 5-butyl-indole-3-carbinol, 5-pentyl-indole-3-carbinol, 5-methoxy-indole-3-carbinol, 5-ethoxy-indole-3-carbinol, 5-propyloxy-indole-3-carbinol, 5-butyloxy-indole-3-carbinol, 5-amxyloxy-indole-3-carbinol, N-methyl-indole-3-carbinol, N-ethyl-indole-3-carbinol, N-propyl-indole-3-carbinol, N-butyl-indole-3-carbinol, N-pentyl-indole-3-carbinol, 2-methyl-indole-3-carbinol, 2-ethyl-indole-3-carbinol, 2-propyl-indole-3-carbinol, 2-butyl-indole-3-carbinol and 2-pentyl-indole-3-carbinol.

10. (currently amended) A method for an effective treatment of a ~~tumour~~ tumor by combination therapy, comprising administering an effective antitumor amount of ET-743 in combination with indole-3-carbinol or one or more derivatives or pharmaceutically acceptable salts thereof, wherein the indole-3-carbinol derivatives are selected from:

5-methyl-indole-3-carbinol, 5-ethyl-indole-3-carbinol, 5-propyl-indole-3-carbinol, 5-butyl-indole-3-carbinol, 5-pentyl-indole-3-carbinol, 5-methoxy-indole-3-carbinol, 5-ethoxy-indole-3-carbinol, 5-propyloxy-indole-3-carbinol, 5-butyloxy-indole-3-carbinol, 5-amxyloxy-indole-3-carbinol, N-methyl-indole-3-carbinol, N-ethyl-indole-3-carbinol, N-propyl-indole-3-carbinol, N-

butyl-indole-3-carbinol, N-pentyl-indole-3-carbinol, 2-methyl-indole-3-carbinol, 2-ethyl-indole-3-carbinol, 2-propyl-indole-3-carbinol, 2-butyl-indole-3-carbinol and 2-pentyl-indole-3-carbinol.

11. (currently amended) [[A]] The method according to claim 9 or 10, wherein the indole-3-carbinol or one or more derivatives or pharmaceutically acceptable salts thereof is administered to a patient prior to treatment with ET-743.

12. (previously presented) The method according to claim 9 or 10, wherein the indole-3-carbinol or one or more derivatives or pharmaceutically acceptable salts thereof and ET-743 form part of the same medicament.

13. (previously presented) The method according to claim 9 or 10, wherein the indole-3-carbinol or one or more derivatives or pharmaceutically acceptable salts thereof and ET-743 form part of separate medicaments.

14. (previously presented) The method according to claim 9 or 10, wherein the indole-3-carbinol or one or more derivatives or pharmaceutically acceptable salts thereof is indole-3-carbinol.

15. (previously presented) The method according to claim 9 or 10, wherein the method further comprises administering an additional hepatoprotector.

16. (previously presented) The method according to claim 15, wherein the additional hepatoprotector is dexamethasone.

17. (previously presented) The method according to claim 9 or 10, wherein the patient has a cancer selected from sarcoma, osteosarcoma, ovarian cancer, breast cancer, NSCL carcinoma,

melanoma, head and neck cancer, colorectal cancer, mesothelioma, renal cancer, endometrial cancer and lung cancer.

18. (canceled)

19. (canceled)

20. (canceled)

21. (previously presented) The method according to claim 9 or 10, wherein the indole-3-carbinol or derivatives or pharmaceutically acceptable salts thereof is selected from indole-3-carbinol or pharmaceutically acceptable salts thereof.

22. (new) The method according to claim 17, wherein the cancer is selected from sarcoma, osteosarcoma, ovarian cancer, breast cancer, and endometrial cancer.

23. (new) The method according to claim 22, wherein the cancer is breast cancer.

24. (new) The method according to claim 11, wherein the indole-3-carbinol or one or more derivatives or pharmaceutically acceptable salts thereof is administered for at least 3 days prior to treatment with ET-743.

25. (new) The method according to claim 11, wherein the indole-3-carbinol or one or more derivatives or pharmaceutically acceptable salts thereof is administered for at least 6 days prior to treatment with ET-743.

26. (new) The method according to claim 14, wherein the indole-3-carbinol is administered orally in a dosage of 0.5 to 3 g/m² per day.

27. (new) The method according to claim 26, wherein the indole-3-carbinol is administered for at least 3 days prior to treatment with ET-743.

28. (new) The method according to claim 26, wherein the indole-3-carbinol is administered for at least 6 days prior to treatment with ET-743.

29. (new) A method for effectively treating a tumor with Ecteinascidin 743 (ET-743) while reducing the undesirable hepatotoxic side effects of ET-743, said method comprising administering to a patient in need thereof an effective amount of ET-743 in combination with indole-3-carbinol or a pharmaceutically acceptable salt thereof, wherein said tumor is selected from the group consisting of sarcoma, osteosarcoma, ovarian cancer, breast cancer, and endometrial cancer.

30. (new) A method for effectively treating a tumor with Ecteinascidin 743 (ET-743) while reducing the undesirable hepatotoxic side effects of ET-743, said method comprising administering to a patient in need thereof an effective amount of ET-743 in combination with indole-3-carbinol, wherein indole-3-carbinol is administered orally in a dose of 0.5 to 3 g/m² per day for at least 3 days prior to administration of ET-743, and wherein said tumor is selected from the group consisting of sarcoma, osteosarcoma, ovarian cancer, breast cancer, and endometrial cancer.

31. (new) The method according to claim 29 or 30, wherein said tumor is breast cancer.

32. (new) The method according to claim 29 or 30, wherein said method further comprises administering dexamethasone.